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## CLINICAL RESEARCH

# Reduction of radiation delivered to patients undergoing invasive coronary procedures. Effect of a programme for dose reduction based on radiation-protection training

Réduction de l'irradiation du patient lors des procédures de cardiologie interventionnelle. Effet d'un programme de réduction de doses basé sur une formation à la radioprotection

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### KEYWORDS

Radiation protection;  
Training;  
Dose area product;  
Coronary angiography;  
Percutaneous coronary intervention

### Summary

**Background.** — Exposure of patients to radiation from invasive cardiac procedures is high and may be deleterious.

**Aims.** — To assess the effectiveness of a dose-reduction programme based on radiation-protection training, according to the recommendations of the Euratom Council, the International Commission on Radiological Protection and the French Society of Cardiology.

**Methods.** — In this single-centre survey, dose-area product (DAP, Gy.cm<sup>2</sup>), fluoroscopy time (minutes) and number of runs were evaluated in 3285 consecutive procedures (2077 coronary angiographies [CAs], 1208 percutaneous coronary interventions [PCIs]), performed one year before (2005) and two years after (2006 to 2007) implementation of a programme for radiation dose-reduction. The programme included a 2-day training course in radiological protection for all medical and paramedical staff and recommendations for routine use of low fluoroscopic

**Abbreviations:** CA, coronary angiography; PCI, percutaneous coronary intervention; DAP, dose × area product; BMI, body mass index; IVUS, intravascular coronary ultrasound.

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## MOTS CLÉS

Formation à la  
radioprotection ;  
Coronarographie ;  
Angioplastie  
coronaire ;  
Produit  
dose  $\times$  surface

and acquisition pulse rates (6.25 and 12.5 i/s, respectively), large field size (23 cm), maximal collimation and optimal X-ray tube/patient/detector distances. Routine left ventriculography was discouraged. The radial approach was used in > 80% of the procedures.

**Results.** — Compared with 2005, a significant 50% reduction in DAP was observed in 2006 and 2007 during CA (median [interquartile range] 53 Gy.cm<sup>2</sup> [33–84] vs 26 [16–43] and 21 [14–32], respectively;  $p < 0.0001$ ) and PCI (125 Gy.cm<sup>2</sup> [78–184] vs 49 [31–79] and 44 [27–66], respectively;  $p < 0.0001$ ). Fluoroscopy time and number of runs did not vary significantly in 2006, and decreased slightly in 2007, likely due to an important reduction in rate of left ventriculographies (from 32 to 4%). Inter-operator variability in DAP was reduced.

**Conclusion.** — Training in radiation protection for interventional cardiologists and use of simple and cost-free dose-reduction techniques were associated with a 50% reduction in radiation exposure to patients undergoing invasive cardiac procedures, without any loss of diagnostic information.

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## Résumé

**Background.** — Les procédures de cardiologie interventionnelle sont parmi les plus irradiantes pour le patient et comportent certains risques, notamment de cancers radio-induits.

**Objectifs.** — Cette étude a pour but d'évaluer l'efficacité d'un programme de réduction des doses de rayonnement au patient, basé sur une formation à la radioprotection suivant les recommandations de l'Euratom Council, de l'International Commission on Radiological Protection, et de la Société française de cardiologie.

**Méthode.** — Dans cette étude monocentrique prospective, le produit Dose par Surface (PDS en Gy.cm<sup>2</sup>), le temps de radioscopie (TS en minute) et le nombre de séquences (NS) ont été analysés pour 3285 procédures consécutives (2077 coronarographies [CA] et 1208 angioplasties coronaires percutanées [ACP]), réalisées une année avant (2005) et deux années après (2006–2007) la mise en place d'un programme de réduction des doses. Ce programme a associé (1) une formation de deux jours à la radioprotection pour l'ensemble du personnel médical ; (2) des recommandations aux opérateurs pour l'utilisation en routine de flux réduits en fluoroscopie et en cinégraphie (6,25 et 12,5 i/s, respectivement), de champs larges (23 cm), d'une collimation maximale, une optimisation des distances tube/patient/détecteur, et l'abandon de la ventriculographie gauche systématique. La voie radiale a été utilisée dans plus de 80 % des procédures.

**Résultats.** — Comparativement à 2005, une réduction significative de plus de 50 % du PDS a été observée en 2006 et 2007 pour les CA (médiane [quartiles] 53 Gy.cm<sup>2</sup> [33–84] vs 26 [16–43] et 21 [14–32], respectivement,  $p < 0,0001$ ), et pour les ACP (125 Gy.cm<sup>2</sup> [78–184] vs 49 [31–79] et 44 [27–66], respectivement,  $p < 0,0001$ ). Les TS et NS n'ont pas varié significativement en 2006 et ont légèrement diminué en 2007, probablement en lien avec la réduction importante des ventriculographies gauches (de 32 à 4 %). La variabilité inter-opérateurs du PDS a été également réduite.

**Conclusion.** — Une formation courte à la radioprotection, telle qu'elle est proposée par la Société française de cardiologie, et la mise en place de mesures simples et non coûteuses de réduction des doses de RX ont été associées à une diminution de 50 % de l'exposition du patient lors des procédures de cardiologie interventionnelle coronaire, sans perte d'information diagnostique.

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## Introduction

X-ray exposure of patients during CA and PCI is high and may have some deleterious effects including an increased risk of developing cancer [1–5]. Reducing the dose of radiation delivered to patients has a major impact by decreasing the risks for both the patient and the in-room medical and paramedical staff. According to the Euratom Council directive [1] and the International Commission on Radiological Protection [2,3], training in radioprotection for cardiologists, and analysis of exposure of patients undergoing

medical procedures using ionizing radiation and comparisons to reference values, are highly recommended. A previous analysis from our practice [6] demonstrated that the median X-ray doses delivered to patients during PCI decreased between 2002 and 2005 but remained higher than European reference values [7], whereas fluoroscopy time and number of runs/frames were low. We therefore implemented a programme for dose reduction in interventional cardiology in our institution. The purpose of this study was to assess the impact of this programme on the X-ray dose delivered to patients.

## Methods

### Equipment and procedures

We used a digital, single C-arm Siemens Hicor®, installed in 1998, equipped with a three-field 23 cm image intensifier (23/17/13 cm), adjustable rectangular field limitations and one-blade contour filter. Dose rate options were available for fluoroscopy (6.25, 12.5 or 25 frames/second) and for cinegraphy (12.5, 25 and 50 frames/second). CA and PCI were performed by five experienced physicians. In 2005, number of runs, choice and angulation of the projections, intensifier field size, collimation and realization of left ventriculography were at the operator's discretion. From January 2006, operators were encouraged to follow the internal recommendations for X-ray dose reduction (see below). A right radial approach was used in 81% of procedures.

### Radiation dose-reduction programme

A radiation dose-reduction programme was implemented in the catheterization laboratory in January 2006. As the first part of the programme, all medical and paramedical staff participated in a national 2-day training course in radio-protection (15 training hours). The course was organized in partnership with the working group 'Athérosclérose et Cardiologie Interventionnelle' (GACI) of the French Society of Cardiology, according to the European and French regulatory authorities [1,8]. The time schedule of the training programme was as follows: December 2005 (one operator), March 2006 (two operators, two nurses), December 2006 (two operators, two nurses) and March 2007 (one nurse).

The second part of the programme consisted of the implementation of simple technical recommendations for operators, aimed at reducing the radiation dose delivered to the patient. From 1 January 2006, operators were encouraged to routinely use: (1) low fluoroscopic and cine pulse rates (6.25 and 12.5 frames/second, respectively); (2) a large intensifier field size (23 cm) with an a posteriori numeric magnification; (3) maximal collimation; and (4) optimal X-ray tube/patient/image intensifier distances (maximal source-patient distance, minimal patient-image intensifier distance). Routine left ventriculography was discouraged, and was contraindicated when left ventricular ejection fraction was assessed using a non-invasive method. The number of runs, choice and angulation of the projections necessary to obtain the best possible analysis of the coronary arteries were not limited.

### Study population

Radiation parameters have been registered prospectively in our institution since 2002, for all coronary diagnostic and therapeutic procedures [6]. To evaluate the effect of the programme and training course, we analysed 3285 consecutive procedures from the registry (CA,  $n=2077$ ; PCI,  $n=1208$ ), performed from 2005 to 2007 (i.e., the year before, and two years after, implementation of the programme for dose reduction). Procedures performed in 2005 were considered as the control group. Baseline characteristics of patients, radiation parameters and variables associated with the radiation dose, such as weight, BMI,

emergency procedures and multilesion revascularization procedures, were compared between 2005 and 2006 to 2007.

### Radiation parameters

Three parameters related to the patient's irradiation were measured: (1) the DAP ( $\text{Gy}\cdot\text{cm}^2$ ) was measured using a flat, light-transparent ionization Diamentor (PTW, Freiburg, Germany). DAP is related to the effective dose equivalent; it allows an estimation of the stochastic risk and is a potential quality indicator [5]; (2) fluoroscopy time in minutes; and (3) number of runs, since the number of frames was not available routinely with our equipment. Radiation parameters were available for 3249 (99%) procedures.

### Statistical analysis

Continuous data are presented as median [interquartile range, IQR]. Non-normally distributed continuous data, such as DAP, were log-transformed for comparisons by ANOVA, and post hoc pair-wise comparisons between years were done by Scheffé or Dunnett tests. Categorical variables are presented as count and percentage, and were compared by the chi-square test. Correlations between DAP and fluoroscopy time were analysed separately for CA and PCI by univariate and multivariable linear regression models, controlling for age, gender and factors associated with DAP in univariate analysis (BMI, operator, radial/femoral route, emergency procedure). The effect of time on the association between DAP and fluoroscopy time was tested by introducing an interaction term in the model. Because of multiple testing, a  $p$  value  $<0.01$  was considered significant. All statistical analyses were carried out with the SPSS® version 12.0 software (SPSS Inc., Chicago, IL).

## Results

Table 1 provides the baseline characteristics of the population. There was no difference between 2005, 2006 and 2007 regarding age, sex-ratio, BMI, clinical data, rate of emergency procedures for acute myocardial infarction, frequencies of multivessel disease and multivessel PCI, and success rates of PCI. Intracoronary ultrasound was performed more frequently in 2006 and 2007 than in 2005.

Table 2 shows the time course of radiation parameters between 2005 and 2007. Compared with 2005, DAP was significantly reduced in 2006 and 2007 for CA (overall  $p < 0.0001$ ) and for PCI (overall  $p < 0.0001$ ). The programme was associated with a reduction in number of procedures delivering high doses ( $> 250 \text{ Gy}\cdot\text{cm}^2$ ), which are potentially the most harmful (Fig. 1). In 2007, 93% of CAs and 89% of PCIs delivered radiation doses lower than the European and national reference values ( $57 \text{ Gy}\cdot\text{cm}^2$  for CA;  $94 \text{ Gy}\cdot\text{cm}^2$  for PCI) [7,9]. Fluoroscopy time and number of runs, which were not directly affected by the programme, did not change significantly between 2005 and 2006, and remained below the European references values (fluoroscopy time, 6 min for CA; 16 min for PCI) (Table 2). Small but significant decreases in number of runs and fluoroscopy time were observed in 2007 compared with 2006, probably due in part to the reduction in rate of left ventriculographies. Left ventricu-

**Table 1** Baseline characteristics of study population and procedural information.

	2005 <i>n</i> = 1088	2006 <i>n</i> = 1059	2007 <i>n</i> = 1138	<i>p</i> value
<b>Patients</b>				
Age	64.8 ± 13.1	65.1 ± 13.4	65.1 ± 12.5	0.90
Men (%)	790 (72)	732 (69)	803 (71)	0.20
BMI (kg/m <sup>2</sup> )	26.3 ± 4.5	26.3 ± 4.3	26.6 ± 4.6	0.29
BMI > 30 kg/m <sup>2</sup> , <i>n</i> (%)	168 (17)	181 (17)	195 (17)	0.94
Stable ischaemic disease, <i>n</i> (%)	559 (51)	517 (49)	605 (53)	0.16
Acute coronary syndrome, <i>n</i> (%)	430 (41)	447 (42)	452 (40)	
Non-ischaemic, <i>n</i> (%)	99 (9)	95 (10)	81 (7)	
Multivessel disease, <i>n</i> (%)	296 (27)	310 (29)	343 (30)	0.56
<b>Procedure</b>				
CA, <i>n</i> (%)	677 (62)	670 (63)	730 (64)	0.85
CA followed by ad hoc PCI, <i>n</i> (%)	358 (33)	334 (32)	357 (31)	
PCI alone, <i>n</i> (%)	53 (5)	55 (5)	51 (5)	
Radial approach, <i>n</i> (%)	852 (78)	878 (83)	920 (81)	0.03
Emergency procedure, <i>n</i> (%)	169 (15)	135 (13)	157 (14)	0.20
IVUS, <i>n</i> (%)	6 (1)	40 (4)	36 (3)	< 0.0001
Number of lesions treated (overall)	591	585	601	-
Number of stents implanted per patient	1.5 ± 0.7	1.6 ± 0.8	1.5 ± 0.8	0.93
Multivessel PCI, <i>n</i> (%)	64 (16)	74 (19)	66 (16)	0.44
Success of PCI (lesions), <i>n</i> (%)	573 (97)	567 (97)	579 (96)	0.44

Continuous data expressed as mean ± SD.

BMI: body mass index; CA: coronary angiography; PCI: percutaneous coronary intervention; IVUS: intravascular coronary ultrasound.

lography was performed in 32% of the CA in 2005, 11% in 2006 and only 4% in 2007 ( $p < 0.0001$ ). The reduction in DAP was not explained by the decrease in left ventriculography only, since a significant decrease in DAP was also observed when comparing procedures without left ventriculography (CA, 47 Gy.cm<sup>2</sup> [31–77] in 2005; 25 [15–40] in 2006; 21 [13–30] in 2007;  $p < 0.0001$ ) (PCI, 117 Gy.cm<sup>2</sup>

[77–182] in 2005; 47 [29–76] in 2006; 43 [27–63] in 2007;  $p < 0.0001$ ).

Correlations between DAP and fluoroscopy time are shown in Fig. 1. DAP was significantly associated with fluoroscopy time, before and after adjustment for age, gender, BMI, operator, arterial route and emergency procedures. Fig. 1 shows that the slope of the regression line between

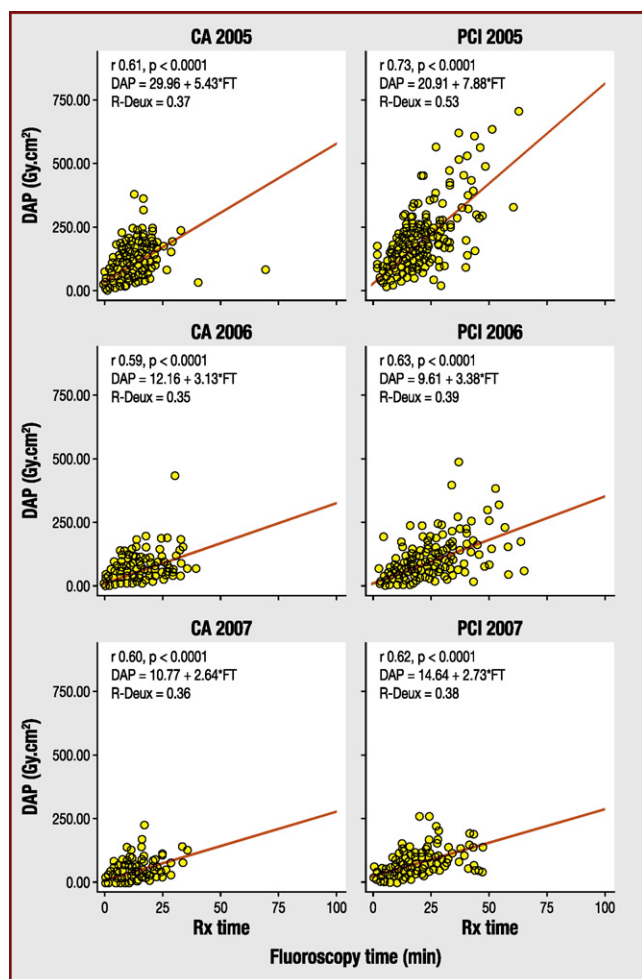
**Table 2** X-ray exposure parameters before (2005) and after (2006 to 2007) implementation of the programme to reduce radiation dose.

	2005 <i>n</i> = 1072	2006 <i>n</i> = 1049	2007 <i>n</i> = 1128	<i>p</i> value (overall)	<i>p</i> value (2006 vs 2005)	<i>p</i> value (2007 vs 2006)
<b>Coronary angiography</b>						
DAP (Gy.cm <sup>2</sup> )	53 [33–84]	26 [16–43]	21 [14–32]	< 0.0001	< 0.0001	< 0.0001
Fluoroscopy time (min)	5.4 [3–9]	5.6 [3–9]	4.4 [3–8]	0.002	0.65	< 0.0001
Number of runs ( <i>n</i> )	13 [11–16]	12 [10–14]	11 [10–13]	< 0.0001	0.12	< 0.0001
<b>PCI (elective and ad hoc pooled)</b>						
DAP (Gy.cm <sup>2</sup> )	125 [78–184]	49 [31–79]	44 [27–66]	< 0.0001	< 0.0001	0.001
Fluoroscopy time (min)	14 [10–20]	14 [9–22]	12 [8–18]	< 0.0001	0.53	< 0.0001
Number of runs ( <i>n</i> )	25 [21–32]	23 [18–29]	23 [18–7]	0.11	0.36	0.59
Left ventriculography (%)	352 (32)	113 (11)	40 (4)	< 0.0001	-	-

Continuous data expressed as median [interquartile range].

DAP: dose × area product; PCI: percutaneous coronary intervention.

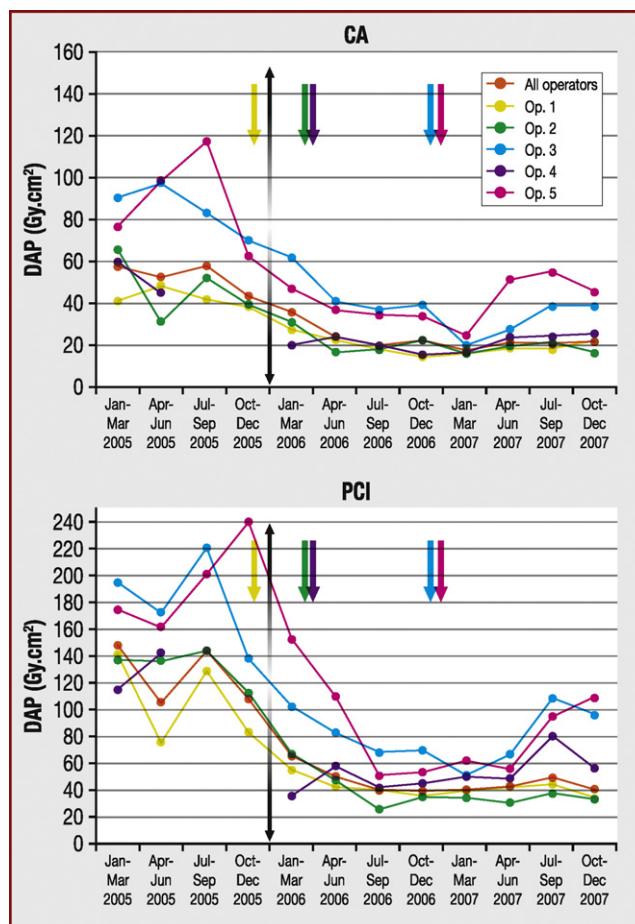




**Figure 1.** Correlations between dose × area product (DAP, Gy.cm<sup>2</sup>) and fluoroscopy time (minutes) for coronary angiography (CA) and percutaneous coronary intervention (PCI), before (2005) and after (2006 and 2007) implementation of the programme for dose reduction.

DAP and fluoroscopy time decreased in 2006 and 2007, compared with 2005. The effect of time on the association between DAP and fluoroscopy time was confirmed by multivariable linear regression including in the models an interaction term, which was highly significant for CA (coefficient  $b = -1.44 \pm 0.14, p < 0.0001$ ) and for PCI (coefficient  $b = -2.94 \pm 0.20, p < 0.0001$ ).

The time course of DAP associated with each operator between 2005 and 2007 is shown in Fig. 2. This analysis demonstrates an important reduction in DAP for all operators in the months following implementation of the programme, and a reduction in the inter-operator variability. Maximal inter-operator absolute difference of median DAP was reduced between 2005 and 2007 from 42 to 18 Gy.cm<sup>2</sup> for CA and from 103 to 32 Gy.cm<sup>2</sup> for PCI. Fig. 2 also suggests that the effect of training is maximal within the three months following the training course, and tends to decrease after three months. There was a trend towards an association between higher volume of activity and lower DAP among operators, but the tests were not statistically significant (data not shown).



**Figure 2.** Time course of dose × area product (DAP, median value in Gy.cm<sup>2</sup>) between 2005 and 2007, by operator, for coronary angiography (CA, top) and percutaneous coronary intervention (PCI, bottom). Black arrow indicates the date of implementation of the programme for dose reduction; small coloured arrows indicate the time of radiation protection training for each operator.

## Discussion

This study shows how very simple radiation-reduction techniques enabled us to reduce median DAP far below common values for CA and PCI [7,9–11]. Procedures that utilize ionizing radiation should be performed in accordance with the As Low As Reasonably Achievable (ALARA) principle [2,3]. The dose during catheter angiography depends upon several fixed or relatively fixed factors, such as the patient's BMI, procedural complexity, emergency circumstances, workload, operator experience, target vessel involved in PCI and catheterization laboratory equipment [10,12]. It is also highly dependent on factors that may be controlled by the operator, and various techniques aimed at reducing the dose have therefore been proposed [3,5,10,13,14]. In the present report, we used very simple and cost-free strategies to minimize the radiation dose to patients and in-room personnel. Kuon et al. demonstrated that to reduce the fluoroscopy and fluorography times, the number of views and to select less irradiating projections was highly effective and resulted in very low levels of DAP for CA (12.9 Gy.cm<sup>2</sup>), elective PCI (13.3 Gy.cm<sup>2</sup>) and ad hoc PCI (25.9 Gy.cm<sup>2</sup>).

[13,14]. Our programme did not recommend that operators modify these parameters, because it could reduce the operators' adherence to the programme. Moreover, fluoroscopy time remained below the recommended values for CA and PCI [7,9]. Additional reductions in fluoroscopy time, which remain associated with DAP after the programme (as shown in Fig. 1), should lower exposure still further. A decrease in the rate of systematic left ventriculography, which may account for 10 to 15% of the total dose during a CA, does not by itself explain the global reduction in radiation dose, since an analysis from procedures without ventriculography showed a similar reduction in DAP between 2005, and 2006 to 2007.

The operators' overall adherence to the programme was good, as illustrated in Fig. 2. Training in radiation protection seems to have a major impact on the overall dose reduction, and on the reduction of inter-operator variability. The respective roles of local recommendations for dose reduction and radiation reduction training are difficult to identify in the present study. The time course of DAP for individual operators strongly suggests that both approaches are complementary. The theoretical background given during the training programme improves understanding about these changes in practice and therefore the medical and paramedical team's adherence to the programme. Conversely, the programme for dose reduction was a direct and coordinated application of the guidelines, with a measurable effect. However, despite the implementation of a local programme for dose reduction, the impact of the training on DAP appeared to be maximal within the three months following the lectures, and then to decrease (rebound effect).

## Potential implications of the study

Although it has been underestimated by interventional cardiologists for a long time, radiation exposure of operators and patients is currently a major concern. Based on assumptions from the International Commission on Radiological Protection, the total risk for the development of fatal cancer has been estimated as one for every 1300 patients subjected to coronary intervention [12], and between 1/3000 and 1/9000 for diagnostic procedures [15]. Even though improvements in radiological equipment have reduced X-ray dose rates, the number and complexity of fluoroscopically guided procedures increase and may also expose the patient to deterministic radiation-induced injuries such as skin ulceration and necrosis [4,5]. In 2006, 272,000 CAs and 121,000 PCIs were performed in France (unpublished data from the French Cardiology Society), more than 620,000 PCIs are performed annually in Europe [16] and more than 1.2 million are performed annually in the United States [17]. Moreover, coronary patients are increasingly exposed to iterative diagnostic and therapeutic techniques of cardiac imaging using ionizing radiation, such as CA (average equivalent dose 5–10 mSv), PCI (7–20 mSv), cardiac nuclear scintigraphy (6–15 mSv) and, more recently, computed tomography coronary angiography (4–21 mSv). This may result in high cumulative doses and in an increased stochastic risk [5,10,18,19]. The present data imply that the exposure of patients undergoing CA and PCI may easily be reduced, consequently decreasing the carcinogenic effect of radiation. Since there is a linear relationship between DAP,

effective dose equivalent and risk of cancer [2–4,12,15], a 50% reduction in radiation dose during CA and PCI is likely to lead to a direct 50% risk reduction for developing fatal X ray-induced cancer as well. Last, in addition to individual radiation protection (lead shielding devices, lead apron, glasses, and gloves), reduction in the X-ray dose to the patient also reduces the exposure of medical and paramedical staff working in the catheterization laboratory.

## Study limitations

This is a single-centre survey, whose results may not extend to other centres. However, according to the characteristics of patients, procedures and levels of X-rays doses at baseline, our centre seems to be representative of the majority of catheterization laboratories. In 2005, DAP and fluoroscopy time levels were near the European reference values, defined as the 75<sup>th</sup> percentile of means observed in the different participating centres, and our centre was at the average position among centres participating in the French survey in 2006 [9]. Second, this was a non-randomized study, and historical comparisons do not allow conclusions of causality. However, the present data are drawn from a prospective registry including all consecutive procedures, without any exclusions. Biases, always possible, seem unlikely since equipment and operators remained the same during the study period, and the characteristics of patients and procedures were similar. The only changes in procedures, except for those induced by the dose-reduction programme, were a trend towards a more radial route, multivessel PCI and intravascular ultrasound procedures, which are classically associated with a higher exposure. Third, impact of the radiation-reduction techniques on the diagnostic performance of CA and the feasibility and security of PCI have not been formally tested in this study. The definition of the images acquired using a large field (23 cm) with a posteriori numerical magnification is, for practical purposes, similar to that obtained when using 16 or 13 cm fields, which are associated with a significant increase in skin-dose rates. The PCI procedural success rate was not modified by the programme. In some PCI procedures, however, magnified fields may be necessary, especially when crossing a complex lesion with the guide wire. Low fluoroscopy rates were well accepted by operators. Maximal collimation should be used with caution during PCI using a hydrophilic guide-wire because of the risk of distal coronary perforation.

In conclusion, training in radiation protection for interventional cardiologists and the use of simple dose-reduction techniques is associated with a 50% reduction in radiation exposure of patients undergoing invasive cardiac procedures, without loss in image quality. This dose reduction is likely to have a significant impact on the risk of radiation-induced morbidity for both patients and operators.

## Conflict of interest

None.

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